A surgeon saw a need. We listened. Our Biodesign Fistula Plugs are a minimally invasive option for fistula repair. The plugs have been shown to minimize risk of postoperative incontinence\(^1\) and can be considered an initial treatment option for fistulas.\(^2\)


Note: The name of our product has changed since this trial was published.
**Biodesign Anal Fistula Plug Set**

Used for implantation to reinforce soft tissue where a rolled configuration is required, for repair of anorectal fistulas.

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Reference Part Number</th>
<th>Size (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>G53614</td>
<td>C-AFPS-0.6X9.5</td>
<td>0.6 x 9.5</td>
</tr>
</tbody>
</table>

Biodesign Fistula Plug Set

Used for implantation to reinforce soft tissue for repair of rectovaginal or anorectal fistulas.

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Reference Part Number</th>
<th>Size (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>G54612</td>
<td>C-FPS-0.2</td>
<td>0.2</td>
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<tr>
<td>G54613</td>
<td>C-FPS-0.4</td>
<td>0.4</td>
</tr>
<tr>
<td>G54614</td>
<td>C-FPS-0.7</td>
<td>0.7</td>
</tr>
</tbody>
</table>

**Cook® Fistula Brush**

Used to identify, clean, or debride a rectal fistula tract and facilitate placement of the Biodesign Fistula plugs.

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Reference Part Number</th>
<th>Length (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>G48527</td>
<td>J-FB-100</td>
<td>46</td>
</tr>
</tbody>
</table>

Some products or part numbers may not be available in all markets. Contact your local Cook representative or Customer Service for details.

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**Customer Service**

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**Biodesign® Anal Fistula Plug**

**INTENDED USE:** The Cook® Biodesign® Anal Fistula Plug is for implantation to reinforce soft tissue where a rolled configuration is required, for repair of anorectal fistulas. The plug is supplied sterile and is intended for one-time use.

**CONTRAINDICATIONS:** This plug is derived from a porcine source and should not be used in patients sensitive to porcine materials. - Not for vascular use.

**PRECAUTIONS:** This device is designed for single use only. Attempts to reprocess, resterilize, and/or reuse may lead to device failure and/or transmission of disease. - Do not reprocess. Discard all open and unused portions. - Plug is sterile if the package is dry, unopened, and undamaged. Do not use if the package seals broken. - Discard plug if mishandling has caused possible damage or contamination if the plug is past its expiration date. - Do not implant the plug in a grossly infected or abscessed fistula tract. - A tract should be used only where there is evidence of acute inflammation, purulence, or excessive drainage. Allow the tract to mature and stabilize for six to eight weeks before placing the plug. - Ensure that the plug is rehydrated prior to placement, cutting, or suturing. - Removal of the plug in tract less than 1 cm in length can result in incomplete incorporation and/or excision of the device.

**POTENTIAL COMPLICATIONS:** Complications that can occur with the plug include: - Inflammation - Infection - Migration - Abscess - Fistula recurrence. - Suture-associated infection. - Allergic reaction. - Delayed or failed incorporation of the plug if any of the following conditions occur and cannot be resolved, plug removal should be considered. - Infection - Abscess - Acute or chronic inflammation (initial application of surgical graft material may be associated with transient, mild, localized inflammation). - Allergic reaction.

See instructions for use for full product information.

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**Biodesign® Fistula Plug**

**INTENDED USE:** The Biodesign® Fistula Plug is for implantation to reinforce soft tissue for repair of rectovaginal or anorectal fistulas. The device is supplied sterile and is intended for single use.

**CONTRAINDICATIONS:** This product is intended for use by trained medical professionals.

**PRECAUTIONS:** The device is designed for single use only. Attempts to reprocess, resterilize, and/or reuse may lead to device failure and/or transmission of disease. - Do not reprocess. Discard all open and unused portions. - Device is sterile if the package is dry, unopened and undamaged. Do not use if the package seals broken. - Discard device if mishandling has caused possible damage or contamination if the device is past its expiration date. - Do not implant the device in a grossly infected or abscessed fistula tract. - In fistula cases involving evidence of acute inflammation, purulence, or excessive drainage, a draining tract should be used to allow the tract to mature and stabilize for six to eight weeks before placing the plug. - Ensure that the device is rehydrated prior to placement, cutting, or suturing. - Removal of the plug in tract less than 1 cm in length can result in incomplete incorporation and/or excision of the device.

**POTENTIAL COMPLICATIONS:** Complications that can occur with the Fistula Plug include, but are not limited to: - Inflammation - Infection - Migration - Erosion - Creation of fistula tract. - Acute or chronic inflammation involuting evidence of acute inflammation. - Abscess - Fistula recurrence. - Delayed or failed incorporation of the device if any of the following conditions occur and cannot be resolved, device removal should be considered. - Infection - Acute or chronic inflammation (initial application of surgical graft material may be associated with transient, mild, localized inflammation). - Allergic reaction.

See instructions for use for full product information.